AD_____

Award Number: W81XWH-10-1-0840

TITLE: SCI Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population

PRINCIPAL INVESTIGATOR: Lisa J. Gould, MD, PhD

CONTRACTING ORGANIZATION: James A Haley Veterans Hospital

REPORT DATE: October 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
October 2013	Annual	30 Sep 2012-29 Sep 2013

4. TITLE AND SUBTITLE

SCI Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-10-1-0840

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Lisa J. Gould, M.D., Ph.D.

email: lgould44@hotmail.com

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
James A Haley Veterans Hospital

Tampa, FL 33612

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Our preliminary hypothesis is that there are factors, biological and psychosocial, that increase or reduce vulnerability to PrUs among spinal cord injured persons. A retrospective review of 120 randomly sampled charts from patients undergoing the SCI Comprehensive Preventive Health Evaluation between Jan 1 and Dec 31, 2009 was conducted using a data extraction tool based on a set of variables thought to be important in PrU development. This sample, which focuses on outpatient veterans with SCI, represents an older population than previously studied (mean age across all groups=62). 74% sustained their injury more than 10 years ago. 39% of the index sample reported never having a pressure ulcer, while 31% had ≥ 3 pressure ulcers since the time of injury. In this study severity of spinal cord injury based on ASIA and FIM scores, BMI>25, prior hospitalization within the previous year, anemia, and service connection were identified as factors that increase pressure ulcer vulnerability. The study identified body composition with or without spasticity and caregiver activity as two factors that warrant further investigation in a prospective fashion.

15. SUBJECT TERMS
Pressure ulcer risk; spinal cord injury

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	35	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

Page

Introduction:

Most published research that identifies risk factors for development and recurrence of Pressure Ulcers (PrUs) has been conducted in the nursing home elderly or in the SCI Model systems (sponsored by NIDRR) ,which includes primarily acute injuries. The literature examining risk and recurrence of PrUs in the Veteran SCI population, i.e., long-term chronic SCI, focuses on the patients who have already developed PrUs. Those who do not develop PrUs are excluded, thereby excluding a critical 'control' population. Although more than 200 risk factors have been identified as being involved in PrU development, it is not clear how to stratify them into useful guidelines for PrU prevention. This retrospective survey of SCI outpatients completing their annual SCI Comprehensive Preventive Health Evaluation is based on our preliminary hypothesis is that there are factors, biological and psychosocial that increase or reduce vulnerability to PrUs among spinal cord injured persons. The data obtained from this research will be used to identify and stratify the factors that are different between patients who have never had a pressure ulcer and those who suffer from multiple ulcers, with emphasis on modifiable risk factors. Subsequent studies will then refine this list prospectively, leading to the development of evidence-based risk assessment tools and customized interventions that will be tested in future randomized controlled trials.

Body:

Objectives/Specific Aims:

The purpose of this study is to conduct a retrospective chart review. Specifically we intend to refine the list of potential factors that increase or decrease vulnerability of community dwelling SCI persons to PrUs.

Research Design:

Utilizing a computer generated list, 120 patient charts were randomly selected from the nearly 1400 patients with SCI who completed their SCI Comprehensive Preventive Health Evaluation at the James A Haley Veterans Hospital in Tampa between Jan 1 and Dec 31, 2009. Patients with or without pressure ulcers were included. Patients with SCI due to terminal disease, multiple sclerosis of amyotrophic lateral sclerosis were excluded. A data extraction tool was used to compile information known to impact the development of pressure ulcers in persons with SCI. This included demographics, biological and physical factors and psychosocial aspects. The local Institutional Review board for Human Subjects Research and the local Veterans Affairs Research and Development Committee approved the study.

Results:

The mean age across all groups was 62±12.5. 74% of the population studied sustained their spinal cord injury more than 10 years ago, with 35.5% more than 30 years ago. Similar to other VA studies, 98% were male with the majority Caucasian. 43% were quadriplegic. They are also a population with significant co-morbidities: 29.2% currently use tobacco, 37% of those smoke at least one pack per day; 22.7% have BMI >30 and 30% have been diagnosed with depression. More than half had greater than 50% service connection, although not necessarily related to their spinal cord injury.
Of the 120 patients, 39.5% reported never having a pressure ulcer, 29.5% had 1-2 PrUs and 31% had ≥ 3 pressure ulcers since the time of injury. Although 26% healed their pressure ulcers rapidly (0-3 months), 10% of the patients have never successfully healed their ulcer, contending with a chronic open wound. Factors increasing PrU vulnerability include: Violence as a mechanism of injury, FIM score ≤ 87, ASIA-A, BMI ≤ 25, lifetime tobacco exposure ≥30 pack years. Diabetes, age >65 and duration of injury were not significantly different between the three groups and therefore do not appear to be risk factors in this population. Patients with ≥3 PrUs were noted to be anemic and have lower albumin and pre-albumin than those without PrUs. This is likely to be a consequence rather than a cause. The data set also identified a number of variables that are not easily extracted from the electronic medical record (either could not be found or were not present), including contractures, use of specialized support surfaces, means of transportation, mobility, caregiver status, bowel and bladder continence, level of education, mental health status or illicit drug use.

Key Research Accomplishments:

The retrospective survey of 120 patients is complete.

Reportable Outcomes:

1) The manuscript to describe the retrospective survey was submitted to International Wound Journal and rejected. A revision is underway for submission to Medical Hypotheses
2) Based on the difficulty encountered in manually extracting data from the electronic medical record (CPRS) a proposal entitled **Leveraging Information in the EHR to Measure Pressure Ulcer Risk in Veterans with SCI was developed with** Stephen L. Luther, PhD as PI, Gould as one of the Co-I's. This project, which was recently funded by VA HSR&D has the following aims: 1) Develop natural language processing (NLP) programs to identify the occurrence of PrUs; 2) Develop predictive models of occurrence of PrUs based on available structured data for early impact on PrU risk assessment; 3) Develop NLP programs to reliably extract information about potential predictors from text in clinical notes; 4) Combine risk information obtained through structured and text extracted NLP data, and develop robust risk assessment predictive of PrUs.
3) The project was transferred to Geoffrey Harrow, MD, PhD with assistance of the Tampa VA R&D office.

Conclusions:

Pressure ulcers (PrU) are among the most significant complications in Veterans with spinal cord injury (SCI) in terms of quality of life and cost of care. This retrospective study is the first of its kind to describe patient characteristics and pressure ulcer incidence of community dwelling, spinal cord injured veterans. The study has identified body composition with and without spasticity and the number and nature of caregiver hours as two modifiable risk factors that warrant future study in a prospective fashion. The ultimate goal is to develop an SCI-specific tool that can be used by the provider and patient to identify and modify risk factors that lead to pressure ulcer vulnerability, thereby reducing the lifetime risk and burden chronic non-healing wounds.

References:

1. Bates-Jensen BM, Guihan M, Garber SL, Chin AS, Burns SP. Characteristics of recurrent pressure ulcers in veterans with spinal cord injury. *J Spinal Cord Med* 2009;32(1):34-42.
2. Byrne DW, Salzberg CA. Major risk factors for pressure ulcers in the spinal cord disabled: a literature review. *Spinal Cord* 1996;34(5):255-63.
3. Carlson CE, King, R.B., Kirk, P.M., Temple, R., Heinemann, A. Incidence and correlates of pressure ulcer development after spinal cord injury. *J Rehabil Nurs Res* 1992;1 :34-40.
4. Fuhrer MJ, Garber SL, Rintala DH, Clearman R, Hart KA. Pressure ulcers in community-resident persons with spinal cord injury: prevalence and risk factors. *Arch Phys Med Rehabil* 1993;74(1 1):1 172-7.
5. Garber SL, Rintala DH, Hart KA, Fuhrer MJ. Pressure ulcer risk in spinal cord injury: predictors of ulcer status over 3 years. *Arch Phys Med Rehabil* 2000;81(4):465-71.
6. Garber SL, Rintala DH. Pressure ulcers in veterans with spinal cord injury: a retrospective study. *J Rehabil Res Dev* 2003 ;40(5):433-41.
7. Guihan M, Garber SL, Bombardier CH, Goldstein B, Holmes SA, Cao L. Predictors of pressure ulcer recurrence in veterans with spinal cord injury. *J Spinal Cord Med* 2008;31(5): 551-559
8. Henzel MK, Bogie KM, Guihan M, Ho CH. Guest Editorial: Pressure ulcer management and research priorities for patients with spinal cord injury: Consensus opinion from SCI QUERI Expert Panel on Pressure Ulcer Research Implementation. *J Rehabil Res Dev*. 2011;48(3):xi-xxxii.
9. Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: a systematic review. *JAMA* 2006;296(8):974-84.
10. Yarkony GM, Heinemann, A.W. Spinal cord injury: Clinical outcomes from the model systems. In: Stover SL, DeLisa, J.A., Whiteneck, G.G., editor. *Pressure Ulcers.* Gaithersburg, MD: Aspen Publishing, 1995.

Spinal Cord Injury Survey to Determine

Pressure Ulcer Vulnerability in the Outpatient Population

Introduction

Development of pressure ulcers (PrUs) is one of the most common complications of Spinal Cord Injury (SCI). Although there has been a dramatic improvement in life-expectancy for persons with SCI since the 1970's, this is mostly attributed to reduced mortality during the initial 2 years post-injury. Sepsis associated with genitourinary conditions and PrUs remains the major source of morbidity and mortality for those with chronic SCI (1,2). PrUs are one of the major causes of rehospitalization after the initial injury and account for 8% of deaths after SCI. The economic impact of PrUs is large, with the cost of treating a single full thickness PrU estimated at $70,000, leading to $11 billion of US expenditures in healthcare (3). For Veteran patients with SCI the presence of a PrU adds approximately $73,000 to their total annual healthcare cost with annual hospitalization averaging 61 days compared to 9 days for those without PrUs (4). This does not include the tremendous impact on the person with SCI, including time off work; the need for assistance with such things as child care, pet care, and household care; and the impact on the family and/or caretakers.

Unlike the elderly who incur PrUs when hospitalized or in nursing homes, most persons with SCI develop their PrUs as outpatients, while residing in the community (5). For this reason, the actual prevalence of PrUs in the SCI population is currently unknown, with reported figures varying from 8% to 40% and a recurrence rate of up to 79% (6). The Veterans Health Administration is responsible for approximately 26,000 veterans with SCI/D, accounting for 25% of all persons with SCI/D (Spinal Cord Impairment/Disability) in the United States (http://www.queri.research.va.gov/about/factsheets/sci_factsheet.pdf). As our wounded warriors return from Iraq and Afghanistan, VA is faced with management of a small but very challenging

cohort of patients with SCI. Along with SCI, the constellation of injuries for many of these Veterans may include severe pelvic trauma, burn wounds and multiple amputations and/or severe fractures. One can anticipate that the lifetime risk of PrUs in this population will be even higher than what we currently experience. Therefore it is imperative that factors which increase PrU risk be identified and mitigated.

Most published research that identifies risk factors for development and recurrence of PrUs has been conducted in the nursing home elderly or in the SCI Model Systems (sponsored by National Institute on Disability and Rehabilitation Research), which includes primarily younger patients with acute SCI injuries (3,8,9). The literature examining risk and recurrence of PrUs in the Veteran SCI population, i.e., with long-term chronic SCI, focuses on the patients who have already developed PrUs (6,10). Those who do not develop PrUs are excluded from the study samples, thereby excluding a critical "control" population. More than 200 risk factors have been identified as being involved in PrU development (11). For example, immobility and incontinence are common factors for all persons at risk: elderly, newly injured or chronic SCI. However, there is such a wide variety of factors implicated in the literature that are specific to the SCI population that it is not clear how to stratify them to develop useful guidelines for PrU prevention (11-13). Because they are recurrent, severe ulcers are reported for a minority of the general patient population, occurring primarily in the SCI patient population (14,15). It is our premise that the list of potential risk factors affecting PrU vulnerability must be refined so that the people at highest risk can be identified and protected.

The retrospective survey of SCI outpatients completing their annual SCI Comprehensive Preventive Health Evaluation described here is based on our preliminary hypothesis that there are biological and/or psychosocial factors that increase or reduce vulnerability to PrUs among persons with SCI. Our study objective included identifying and stratifying the factors that are different between patients with 0, 1 or ≥ 2 PrUs, with emphasis on modifiable risk factors. The goal of the study is to generate a limited number of refined hypotheses that can be tested in a

prospective fashion and will ultimately lead to the development of evidence-based risk assessment tools and customized interventions to prevent PrUs in SCI persons in the outpatient setting.

Methods

Study Design. This study used cross-sectional observational research design using medical record review.

Participants. A computer-generated random number table was used to select 120 patient charts from nearly 1400 outpatients with SCI who completed their Comprehensive Preventive Health Evaluation (aka "annual exam") at a VA SCI Center between January 1 and December 31, 2009. These evaluations are typically conducted in the outpatient setting, unless the patient is already hospitalized for another reason or lives too far away from the center to complete the entire evaluation as an outpatient. Patients with and without PrUs were included. Patients with SCI due to terminal disease, multiple sclerosis or amyotrophic lateral sclerosis were excluded from the random selection based on ICD-9 coding.

Procedures. The study team developed an electronic data extraction tool, which included demographics as well as physical, medical, and psycho-social variables documented in the literature to be associated with the increased risk of developing PrUs (11,12) and likely to have been assessed and documented in the annual health evaluation.

Data extraction was conducted by three study team members (a nurse practitioner, a medical student and a nurse scientist). The data extraction team members were trained on how and where to find the data in the electronic medical records. Reliability was established among the extraction team members, who practiced together prior to building the data base. A rule book was developed with the first 15 cases, to ensure the data were interpreted and recorded accurately. Team members consulted with one another and the PI on problematic cases. Verification of extracted data elements was conducted by the PI on approximately 10% of the

patient charts. Nonetheless, one of the findings of this study, to be elaborated on in the discussion, relates to the high degree of inconsistency in the Computerized Patient Record System (CPRS) documentation.

Primary outcome. The primary outcome of interest was whether the Veteran with SCI ever developed a PrU. If so, how many, and when did each occur in reference to date of SCI.

Independent Variables. Table 1 lists the variables identified by the study team, the variable definitions and examples of code used by our statisticians, which may assist other studies with analysis. For the purposes of our analysis, we re-coded a number of variables. For example, we created a new variable: “Good Nutrition”, reflecting nutritional status using the recorded albumin and pre-albumin levels at the time of the annual exam (2009). Also, we identified a number of variables with missing data. The sample mean was used for the missing values.

Statistical Analysis

Statistical comparisons between PrU groups (0, 1, 2+ PrUs) were performed using either Student’s t-test, one-way ANOVA or Chi-square, as appropriate. All analyses were performed using SAS (ver. 9.2 Cary, NC) with statistical significance assumed to be $p \leq 0.05$, two-tailed. Bivariate analyses comparing patients with and without PrUs identified a set of independent variables that were significantly different between the two groups. Correlational analyses were conducted to examine potential multicollinearity between the independent variables. The final set of variables was entered into a stepwise regression. Unconditional logistic regression was used to model the probability of at least 1 PrU after adjustment for potential confounders. Odds ratio and 95% confidence intervals are presented.

Human Subjects. The local Institutional Review Board for Human Subjects Research and the Veterans Hospital Research and Development Committee approved a waiver of informed consent and HIPAA for this study.

Results

Sample Demographics. The study sample characteristics are presented in Tables 2 and 3. One patient was excluded from the analysis due to a large amount of missing data. The mean age across all groups was 62 +/- 12.5 years. Seventy four percent of the sample studied sustained their SCI more than 10 years prior to the study and 35.5% had SCI greater than 30 years in duration. Similar to other VA studies, 98% were male, with the majority (56.8%) Caucasian. Nearly half (43%) had tetraplegia. More than half had greater than 50% service-connected status (although not necessarily related to their SCI).

Of the 119 participants, 39.5% had no previous PrUs, 29.5% had 1-2 PrUs and 31% had ≥ 3 PrUs since the time of injury. Of those with at least 1 PrU, the time to healing varied, with 26% PrUs healing rapidly (0-3 months) while 10% of the PrUs were documented as having never been successfully healed, leaving the Veteran to manage chronic open wound(s) for a prolonged period of time. There was no difference in age, level of education or marital status and presence of PrUs. Violence as the etiology of SCI was more common among those with ≥ 1 PrU.

Variable consolidation/multivariable model development. As shown in Table 3, the bivariate analysis found a high number of independent variables that were significantly associated with number of previous PrUs, including: service-connected status, functional independence measure (FIM) score, American Spinal Injury Association (ASIA) score, body mass index (BMI), albumin, pre-albumin, smoking, hospital days for rehabilitation, hospital days in past year, bed mobility, contractures, caregiver hours per day, osteomyelitis, diabetes, and ulcer location (ischium, heel, trochanter, other).

Variables that were significant in the bivariate analyses were examined in a correlational analysis and some were found to be highly correlated with one another (e.g., LOS/LOS rehab).

Stepwise logistic regression was used to model the probability of at least one PrU after adjustment for potential confounders. Odds ratio and 95% confidence intervals are presented in Table 4. An initial model was run containing independent variables representing: good nutrition (albumin > 3.5 or prealbumin > 17), caregiver support (yes/no), ASIA A (yes/no), overweight (BMI > 25), prior hospitalization within previous year, anemia (hemoglobin < 13), current smoker (yes/no), percent service-connected status, and FIM score. Non-statistically significant variables were excluded from the final model. The final model retained ASIA A (yes/no), overweight (BMI > 25), prior hospitalization within previous year, anemia, service-connected percent, and FIM score (Table 4, Figure 1).

Discussion

PrUs are a source of significant morbidity and personal distress for persons with SCI. The focus of our study was on Veterans living with SCI in the community. Our study demonstrates and confirms that PrUs affect a substantial portion of community-dwelling Veterans with SCI. More than one third of the patients coming for their annual exam had multiple PrUs at the time of their exam and two thirds had had at least one PrU since they were injured. In addition to identifying factors that increase PrU risk, we were interested in protective factors, i.e., can we learn something about those persons who don't develop PrUs that may be protective? Contrary to our initial expectations, there were a number of variables that did not distinguish between those with and without PrUs, including factors that have been identified in other studies, e.g., age, race, smoking history, nutrition and diabetes.

Although advanced age has been identified as a PrU risk factor, this was not the case in our study. This is congruent with a meta-analysis by Gelis et al. (16) which showed age did not predict PrUs in the SCI population. Because our sample did not include a wide range of ages, it may have precluded our ability to stratify PrU risk by age or to distinguish age from duration of SCI. It is most likely that duration of SCI is the more important risk factor for PrU risk (17).

Smoking is considered to be a potentially modifiable PrU risk factor (17, 18)... However, in two separate studies, Weaver et al (19) and Rabadi and Vincent (20) saw no correlation between smoking and PrU prevalence while Guihan et al. found an inverse although statistically non-significant relationship between smoking and PrU recurrence: 20.8% smokers with recurrence vs 27.5% smokers with no-recurrence (13). In this study, current smoking and number of packs per day did not bear out as predictors of PrU risk. However, we did find that the total number of pack-years of smoking was significantly higher in those with ≥ 1 PrU compared to those who never had a pressure ulcer ($p=0.003$). It may be that as others have speculated, cumulative smoking history is a proxy for multiple co-morbidities, particularly respiratory-related illness, depression, pain and alcohol use (19) or that PrUs that develop during times of smoking increase the lifetime risk for future PrUs. These conflicting findings require more investigation, as it is well accepted in the surgical literature that smoking impairs healing. There are many reasons to recommend smoking cessation, as the effect of smoking is transient and rapidly improves with smoking cessation (21). Further clarification of the impact of smoking on PrU development, recurrence, and healing would be beneficial, as this is a truly modifiable factor.

One of the most interesting findings of our study is the suggestion of a protective effect of being moderately overweight. BMI is a notoriously poor surrogate marker of obesity and is particularly inaccurate in the chronic SCI population (22). It is well documented that BMI underestimates adiposity in both men and women with SCI. (22,23) BMI in SCI does not distinguish between fat mass and fat-free mass and does not provide information about body fat distribution, therefore Spungen et al. used dual energy X-ray absorptiometry to measure body composition. In their study, compared to able-bodied controls of the same BMI, persons with SCI had 13% more total body fat, significantly decreased total lean tissue mass and a decreased percentage of lean body mass in the legs, trunk and total body (24). This is particularly important when trying to understand the effect of BMI on PrU vulnerability, as

increased abdominal girth concurrent with wasting of the buttock musculature has the potential to alter the pressure distribution in the seated individual. Although the impact of body composition on PrU risk has not been delineated, it is well documented that the loss of skeletal muscle oxidative capacity predisposes individuals to weight gain, Type II diabetes mellitus, and insulin resistance, similar to that seen in obese and elderly populations (25). Thus, the apparent protection afforded by BMI>25 suggests that this cohort of patients may have incomplete SCI or increased spasticity that preserves the muscle mass. Alternatively, we can hypothesize that a small increase in BMI may provide better pressure distribution in some patients. This combination of factors warrants future examination and analysis.

In developing the data extraction tool, we presumed that spasticity would increase PrU vulnerability (26). Although our data did not reveal any difference in pressure ulcer prevalence between those with or without spasticity, documentation of spasticity in this study was based primarily on evidence of pharmacologic treatment. It has previously been shown that spasticity defends against skeletal muscle atrophy, improves peripheral circulation and improves glucose homeostasis (27,28,29). Those with spasticity are likely to have a higher BMI due to preservation of the muscle mass. Thus, in light of the apparent protective effect on body composition and soft tissue metabolism important for wound healing, spasticity may be a positive, i.e., protective factor for PrU vulnerability. This warrants further investigation in the form of a prospective study that includes analysis of spasticity using the modified Ashworth scale, body composition as determined by Spungen et al. (24), and presence of PrUs.

Bowel and bladder management is often a focus of the annual health evaluation for the person with SCI. A causal relationship between bowel or bladder incontinence and PrUs in persons with SCI has been established in some studies (30, 31) although the level of evidence is low (16). Sumiya's study documents presence or absence of urinary incontinence but does not provide an operational definition (30). In persons with SCI, catheter use would be deemed as appropriate bladder management and therefore mitigation of the risk factor unless

incontinence persisted despite the presence of an indwelling catheter. In this retrospective review we were able to determine use of indwelling catheter, but presence or absence of incontinence was rarely noted. It appears other studies have experienced the same difficulty. For example, in a recent article citing urinary incontinence as a risk factor for pressure ulcers it was stated that 83% of the patients were incontinent, however, 99% had urinary catheters (32). Because these data elements were so difficult to define, they were excluded from our final analysis.

To determine "caregiver" we looked for evidence in the CPRS for the Veteran receiving bowel and/or bladder care. The inference is that a caregiver would conduct skin assessments with bowel/bladder care, promote protective behaviors, and be a source of early detection for PrU development (Stage 1). We asked if there is a relationship between having a caregiver and the number of pressure ulcers. We found that there was no significant difference ($p = 0.426$) between the two groups (0 versus ≥ 1 PrUs). This finding could suggest that caregivers do not provide PrU prevention. We further asked if there is a relationship between the amount of time caregivers spent in the home and the number of pressure ulcers the Veteran had sustained. The two groups were significantly different ($p = 0.016$) in that those with ≥ 1 PrUs had significantly more hours per day of care giving. The supposition is that those with more PrUs need more care. But the significant relationship also begs the question of what caregivers could be doing to improve PrU prevention. This relationship between caregivers in the home environment, hours spent caregiving (PrU prevention), and PrU occurrence is intriguing and deserves further exploration. We found only tangential literature outside of the hospital setting to offer an evidence-based discussion regarding this relationship.

Limitations

Conducting chart reviews to retrieve retrospective data is known to be challenging. The VA system has one of the most robust electronic medical records (EMRs) in the United States,

greatly improving the ability to capture data. Nonetheless, our data retrieval experience was similar to that of other investigators.

The chart abstraction tool was developed in collaboration with SCI/D providers who routinely perform the annual comprehensive health exam outlined in VHA Handbook 1176.01. The team consensus was that the variables chosen for chart abstraction were likely to be included in the EMR and would provide critical information about patient characteristics and behaviors associated with PrU risk.

Clear documentation regarding patient lifestyle factors was particularly challenging to locate. This limited our ability to include a number of variables that may be truly modifiable risk factors, e.g.: caregiver availability, caregiver hours spent and care provided; primary transportation method used and use and type of protective sitting, sleeping and driving surfaces and pressure releases used while travelling. To summarize, Table 5 reflects our confidence in the availability and/or accuracy of the data abstracted from the EMR.

Conclusions

PrUs are among the most significant complications in Veterans with SCI in terms of quality of life and cost of care. Similar to patients who develop neuropathic diabetic foot ulcers, patients with SCI may be unaware of tissue damage until it is too late. Without constant vigilance and attention to the skin, reversible soft tissue damage can quickly become an irreversible defect with long-term sequelae. Despite decades of research, evidence for factors that increase PrU risk in persons with chronic SCI is quite limited (16). This study was driven by the quest to develop a risk assessment tool that would better identify patients at risk for pressure ulcer development, but even more importantly to identify factors that may be protective. Thus far very few protective factors have been identified in the literature: college degree, being married, being employed, exercise and healthy diet (33). This retrospective study is a first step in describing patient characteristics and PrU incidence of community-dwelling

Veterans with SCI. The average age (62 years ± 12.5 years) and duration of SCI (74% of the sample studied sustained their SCI more than 10 years prior to the study, 35.5% had SCI greater than 30 years in duration) confirms that community dwelling SCI Veterans are living longer and will therefore benefit from identification of modifiable PrU risk factors. From this research we have identified body composition with or without spasticity as a factor that warrants further investigation. This is particularly interesting because multiple modalities, i.e., diet, exercise, physical therapy and medication could be utilized to preserve muscle mass and bone density, thereby transforming body composition into a protective factor.

The second hypothesis to be further explored is related to our finding that the number of caregiver hours is directly proportional to the number of pressure ulcers. A prospective study would need to provide detail regarding caregiver tasks, the relationship between pressure ulcer incidence and availability of a caregiver and would clarify whether the caregivers are providing PrU prevention measures and early detection. The ultimate goal is to develop an SCI-specific tool that can be incorporated into the electronic health record for use by the provider and patient to identify and modify risk factors that lead to PrU vulnerability, thereby reducing the lifetime risk and burden of chronic non-healing wounds. Such a tool will help identify those patients at highest risk for PrUs so that scarce resources can be focused on those most vulnerable.

References

1. Rish BL, Dilustro JF, Salazar AM, Schwab KA, Brown HR. Spinal cord injury: a 25-year morbidity and mortality study. *Mil Med* 1997;162:141-8.

2. Strauss DJ, Devivo MJ, Paculdo DR, Shavelle RM. Trends in life expectancy after spinal cord injury. *Arch Phys Med Rehabil* 2006;87:1079-85.

3. Reddy M, Gill SS, Rochon PA. Clinician's Corner: Preventing pressure ulcers. *JAMA* 2006;296:974-84.

4. Stroupe KT, Manheim L, Evans CT, Guihan M, Ho C, Li K, Cowper-Ripley D, Hogan TP, St Andre JR, Huo Z, Smith BM. Cost of treating pressure ulcers for veterans with spinal cord injury. *Top Spinal Cord Injury Rehabil* 2011;16:62-73.

5. National Spinal Cord Injury Statistical Center. SCI Facts and Figures at a Glance. (2013). Retrieved at: https://www.nscisc.uab.edu/PublicDocuments/fact_figures_docs/Facts%202013.pdf

6. Bates-Jensen BM, Guihan M, Garber SL, Chin AS, Burns SP. 2009. Characteristics of recurrent pressure ulcers in veterans with spinal cord injury. *J Spinal Cord Med* 2009;32:34-42.

7. Fuhrer MJ, Garber SL, Rintala DH, Clearman R, Hart KA. Pressure ulcers in community-resident persons with spinal cord injury: prevalence and risk factors. *Arch Phys Med Rehabil* 1993;74:1172-7.

8. Yarkony GM, AW Heinemann. Pressure Ulcers. In Stover SL, DeLisa JA, Whiteneck GG, editors. *Spinal cord injury: clinical outcomes from the model systems*. Gaithersburg, MD: Aspen Publishing. 1995: pp. 45-52

9. Carlson CE, King RB, Kirk PM, Temple R, Heinemann A. Incidence and correlates of pressure ulcer development after spinal cord injury. *Journal of Rehabilitation Nursing Research* 1992;1:34-40.

10. Garber SL, Rintala DH. Pressure ulcers in veterans with spinal cord injury: a retrospective study. *J Rehabil Res Dev* 2003;40:433-41.

11. Byrne DW, Salzberg CA. Major risk factors for pressure ulcers in the spinal cord disabled: a literature review. *Spinal Cord* 1996;34:255-63.

12. Garber SL, Rintala DH, Hart KA, Fuhrer MJ. Pressure ulcer risk in spinal cord injury: predictors of ulcer status over 3 years. *Arch Phys Med Rehabil* 2000;81:465-71.

13. Guihan M, Garber SL, Bombardier CH, Goldstein B, Holmes SA, Cao L. Predictors of pressure ulcer recurrence in veterans with spinal cord injury. *J Spinal Cord Med* 2008;31:551-9.

14. Schryvers OI, Stranc MF, Nance PW. Surgical treatment of pressure ulcers: 20-year experience. *Arch Phys Med Rehabil* 2000;81:1556-62.

15. Krause JS, Carter RE, Pickelsimer E, Wilson D. A prospective study of health and risk of mortality after spinal cord injury. *Arch Phys Med Rehabil* 2008; 89:1482-91.

16. Gélis A, Dupeyron A, P Legros, Benaïm C, Pelissier J, Fattal C. Pressure ulcer risk factors in persons with spinal cord injury Part 2: the chronic stage. *Spinal Cord 2009*;47:651-61.

17. Smith BM, Guihan M, LaVela SL, Garber SL. Factors predicting pressure ulcers in veterans with spinal cord injuries. *Am J Phys Med Rehabil* 2008;87:750-7.

18. Consortium for Spinal Cord Medicine Clinical Practice Guidelines. Pressure ulcer prevention and treatment following spinal cord injury: a clinical practice guideline for health-care professionals. *J Spinal Cord Med*. 2001 Spring;24 (Suppl 1): 40S -101S.

19. Weaver FM, Smith B, LaVela SL, Evans CT, Ullrich P, Miskevics S, Goldstein B, Strayer J, Burns SP. Smoking behavior and delivery of evidence-based care for veterans with spinal cord injuries and disorders. *J Spinal Cord Med* 2011;34:35-45.

20. Rabadi MH, Vincent AS. Do vascular risk factors contribute to the prevalence of pressure ulcer in veterans with spinal cord injury? *J Spinal Cord Med* 2011 January; 34(1): 46–51.

21. Sørensen, LT. Wound healing and infection in surgery: the pathophysiological impact of smoking, smoking cessation, and nicotine replacement therapy: a systematic review. *Ann Surg* 2012;255:1069-79.

22. Buchholz AC, Bugaresti JM. A review of Body Mass Index and waist circumference as markers of obesity and coronary heart disease risk in persons with chronic spinal cord injury. *Spinal Cord* 2005;43:513-8.

23. Yarar-Fisher C, Chen Y, Jackson AB, Hunter GR. Body Mass Index underestimates adiposity in women with spinal cord injury. *Obesity* 2012;21:1223-5.

24. Spungen AM, Adkins RH, Stewart CA, Wang J, Pierson RN, Waters RL, Bauman WA. Factors influencing body composition in persons with spinal cord injury: a cross-sectional study. *J Appl Physiol* 2003;95:2398-407.

25. Gorgey AS, Chiodo AE, Zemper ED, Hornyak JE, Rodriguez GM, Gater R. Relationship of spasticity to soft tissue body composition and the metabolic profile in persons with chronic motor complete spinal cord injury. *J Spinal Cord Med* 2010;33:6-15.

26. Atiyeh BS, Hayek SN. Pressure sores with associated spasticity: a clinical challenge. *Int Wound J* 2005;2:77-80.

27. Bauman, WA, Kirshblum SC, Morrison NG, Cirnigliaro CM, Zhang RL, Spungen AM. Effect of low-dose baclofen administration on plasma insulin-like growth factor-1 in persons with spinal cord injury. *J Clin Pharmacol* 2006;46:476-82.

28. Bennegard G-M, Karlsson A-K. Higher glucose uptake in paralysed spastic leg. *Spinal Cord* 2008;46:103-6.

29. Gorgey AS, GA Dudley. Spasticity may defend skeletal muscle size and composition after incomplete spinal cord injury. *Spinal Cord* 2008;46: 96-102.

30. Sumiya T, Kawamura K, Tokuhiro A, Takechi H, Ogata H. A survey of wheelchair use by paraplegic individuals in Japan. Part 2: prevalence of pressure sores. *Spinal Cord* 1997; 35:595-8.

31. Salzberg, CA, Byrne DW, Cayten CG, van Niewerburgh P, Murphy JG, Viehbeck M. A new pressure ulcer risk assessment scale for individuals with spinal cord injury. *Am J Phys Med Rehabil* 1996;75:96-104.

32. Wilczweski P, Grimm D, Gianakis A, Gill B, Sarver W, McNett M. Risk factors associated with pressure ulcer development in critically ill traumatic spinal cord injury patients. *J Trauma Nurs* 2012;19:5-10.

33. Mortenson WB, Miller WC. A review of scales for assessing the risk of developing a pressure ulcer in individuals with SCI. *Spinal Cord* 2008;46:168-75.

Table 1: Independent Variable Definitions and Analysis Code Examples

Variable	Variable Definition	Examples of Code Used for Analysis
Age	2011 minus Year of Birth	
BMI	*Body Mass Index*: Height Weight formula: BMI Formula: divide weight in pounds by height in inches squared, then multiply the results by a conversion factor of 703.	If BMI<25 then overweight= 0; else overweight =1
Gender	Male or Female	
Years since initial injury	2009 -Year of initial injury	
Marital Status	Married, Living with partner, Single, Divorced, Widowed	
Education level	Unknown, HS GED or Grad, some college, college grad, post graduate	
Caregiver	Another person in the home environment that provides bowel and bladder care	If CG =no or CGhours = . or 0, then CGsupport= 0; else CGsupport =1
Caregiver Status	Live-in, visiting, Unknown	
Race/Ethnicity	African American, Asian, Caucasian, Hispanic, Native Hawaiian/Pacific Islander	
Mechanism of Injury	Motor Vehicle; Motor Cycle, Violence, Fall, Sports, Medical, Other, Unknown	
LOI	*Level of Injury*: The level in the spinal cord at which the injury is recorded - ASIA Score	If ASIA_A =no or ASIA_B –D = yes, then newASIA_A= 0; else newASIA_A=1
LOS	*Length of Stay*: Number of days in hospital 1) acute care; 2) rehab; 3) past year	If LOS_hosp in prior year = . or 0 or $\leq$3; then prior_hosp= 0; else prior_hosp=1
FIM	*Functional Independence Measure*: Chart recorded functional ability in 2009	
Mobility	Gait, Gait-assist, Manual Wheel chair, Power Wheelchair	
Cushion	Yes, No, Unknown	
Bed Mobility	Yes, No, Unknown	
Support Surface	Type of bed surface at home	
Transport Surface	Type of sitting surface during transportation	
Employment	Pre and Post Injury employment	
Good Nutrition	Albumin and Pre-albumin	If Albumin $\leq$ 3.5 or pre-albumin < 18, then good_nutrition =0; else good_nutrition=1.

Athletic participation	Minutes per day/days per week	
Spasticity	Yes/No; Medicated	
Contractures	Yes/No; Mild, Moderate, Severe	
Cognitive/Psychiatric Conditions	Mental status: Anxiety, Bipolar, Depression, Personality Disorder, Dementia, Schizophrenia/delusional, Brain damage	
Pressure Ulcer	Length of time to first PrU from date of injury? Number of PrUs? (Since injury) Location of each? How long to heal? Surgery for PrUs? Type of surgery? Flap?	Example of PrU Location: If location= ischial then ischial=1; else ischial=0
Co-Morbidities	DM: Type 1/ Type 2, Hgb A1c, Hgb level, Anemia, CAD, CHF, Pain, Hyper/ Hypothyroid, Heterotrophic ossification, Autonomic dysreflexia, osteomyelitis	Example of Co-morbidities: If hemoglobin < 13, then Anemia=1; else anemia= 0

Table 2. Demographics

Parameter	0 PrU N = 47 N (%)	>= 1 PrU N = 72 N (%)	p
Male	45 (95.7)	72 (100.0)	0.308
Age, yr (mean, sd)	63.1 ± 12.7	60.4 ± 12.0	0.243
Caucasian	26 (55.3)	42 (58.3)	0.933
Education			--
≤ HS	20 (40.0)	31 (43.1)	--
College/College grad	21 (44.7)	24 (33.3)	--
Post college	2 (4.0)	6 (8.3)	--
Unknown	4 (8.5)	11 (15.2)	0.439
Current employment (FT/PT)	4 (8.0)	7 (9.7)	0.999
Married	22 (46.8)	34 (47.2)	0.773
Service connected ≥ 50%	28 (59.6)	32 (44.4)	0.107
Caregiver	20 (42.6)	36 (50.0)	0.426
Caregiver hours/d	2.9 ± 3.3	5.5 ± 6.8	0.016

Note. Values expressed are either mean±SD or n(%).

Table 3. Bivariate Analysis of Clinical Characteristics

	0 PrU N = 47	>= 1 PrU N = 72	P
Mechanism of injury			
MVA	13 (27.7)	25 (34.7)	--
Motorcycle	5 (10.6)	7 (9.7)	--
Violence	2 (4.3)	12 (16.7)	--
Fall	5 (10.6)	7 (9.7)	--
Sports	4 (8.5)	6 (8.3)	--
Med/Surg complication	8 (17.0)	10 (13.9)	--
Other	10 (21.2)	5 (6.9)	0.172
Level of injury			
C1-C7	20 (42.6)	33 (45.8)	--
T/L	27 (57.4)	38 (52.8)	--
Unknown	0 (8.0)	1 (1.4)	0.904
Duration of injury ≥ 10 years	34 (72.3)	53 (73.6)	0.879
FIM	101.8 ± 20.0	84.4 ± 26.5	0.001
ASIA			
A	10 (21.3)	37 (51.4)	--
B-D	37 (78.7)	35 (48.6)	0.015
BMI	28.4 ± 5.7	25.9 ± 4.3	0.007
BMI			
≤ 20	3 (6.4)	7 (9.7)	
20-25	6 (12.8)	23 (31.9)	
26-30	24 (51.1)	29 (40.3)	
> 30	14 (29.8)	13 (18.1)	
Albumin (g/dl)	4.4 ± 0.4	4.1 ± 0.4	0.001
Pre-albumin (mg/dl)	25.3 ± 5.5	21.5 ± 5.6	0.001
Hemoglobin (gm/dl)	14.3 ± 1.8	13.5 ± 3.5	0.151
Tobacco Current	10 (21.3)	25 (34.7)	0.179
Tobacco Past	34 (72.3)	45 (62.5)	0.268
Smoking/ pack years	18.5 ± 18.3	31.2 ± 25.0	0.003
Packs per day	1.0 ± 0.6	1.0 ± 0.6	0.999
COPD	3 (6.4)	10 (13.9)	0.200
Diabetes Mellitus	9 (19.1)	11 (15.3)	0.581
LOS, rehab	79.0 ± 55.6	201.3 ± 145.4	0.001
LOS, hosp in prior year	5.3 ± 17.0	25.9 ± 57.1	0.018
Years since injury	25.7 ± 17.1	22.6 ± 13.8	0.279
Osteomyelitis	0 (0.0)	10 (13.9)	0.066
Spasticity	31 (66.0)	47 (65.3)	0.939
Bed Mobility	41 (87.2)	50 (69.4)	0.025
Contractures	1 (2.1)	13 (18.1)	0.008
Pain (chart)	3.2 ± 3.0	3.0 ± 2.9	0.717
Location (see table doc)			
Ischial	--	38 (52.8)	--

Sacrum	--	5 (6.9)	--
Heel	--	15 (20.8)	--
Trochanter	--	14 (19.4)	--
Other	--	17 (23.6)	--
Hx of Depression	11 (23.4)	24 (33.3)	0.246
Hx of Alcohol	31 (66.0)	49 (68.1)	0.812

Note. Values expressed are either mean±SD or n (%).

Table 4. Odds Ratios and 95% Confidence Intervals for the Prediction of PrU

Parameter	Odds Ratio	95% CI	P			
Good Nutrition	0.64	0.18-2.20	0.475			
Caregiver support	1.99	0.92-4.33	0.082			
Current smoker	1.71	0.76-3.79	0.184			
FIM	0.97	0.96-0.99				
ASIA A	4.02	1.74-9.27	0.001			
Overweight (BMI > 25)	0.32	0.14-0.77	0.010			
Prior Hospitalization	1.79	0.71-4.51	0.215			
Anemia	3.08	1.06-8.94	0.075			
% Service Connected	0.99	0.99-1.00	0.069			

Note. FIM, functional independence measure; BMI, body mass index (kg/m^2)

Table 5: Chart Review Confidence Scale
This scale reflects the chart reviewers confidence that the information needed was likely to be found in the patient chart.

Chart Review Confidence Scale			
Variable	**Variable Delineated**	**Not Confident**	**Highly Confident**
Year of Injury			X
Date of Birth			X
Gender			X
Marital Status			X
Care giver status		X	
Race			X
Ethnicity			X
Body Mass Index (BMI)			X
Nutrition			X
Athletic participation		X	
Mechanism of injury			X
Level of injury			X
Mobility		X	
Length of Stay	# days in acute care	X	
	# of days in Rehab	X	
	# of days in past year	X	
Support Surface (at home)		X	
Career (before/after injury)		X	
Financial		X	
Management of Bowel			X
Management of Bladder			X
Transportation		X	
FIM Score			X
Spasticity			X
Contractures		X	
Substance Abuse		X	
Tobacco Use			X
Cognitive function/ Psychiatric disorders			X
	Time to first pressure ulcer	X	
	# of PrUs since injury	X	

Chart Review Confidence Scale			
Pressure Ulcer history	Location of each PrU		X
	Time to heal	X	
	Surgery for PrU		X
	Type of surgery		X
Co Morbidities			X

From: editorinchief@internationalwoundjournal.com
Subject: International Wound Journal - Decision on Manuscript ID IWJ-14-104 [email ref: DL-SW-4-a]
Date: May 11, 2014 at 2:56 PM
To: lgould44@hotmail.com

11-May-2014

Dear Dr. Gould:

I write you in regards to manuscript # IWJ-14-104 entitled "Spinal Cord Injury Survey to Determine Pressure Ulcer Vulnerability in the Outpatient Population" which you submitted to International Wound Journal.

In view of the criticisms of the reviewer(s) found at the bottom of this letter, your manuscript has been denied publication in International Wound Journal.

Thank you for considering International Wound Journal for the publication of your research. I hope the outcome of this specific submission will not discourage you from the submission of future manuscripts.

Sincerely,
Prof. Keith Harding
Editor in Chief, International Wound Journal
editorinchief@internationalwoundjournal.com

Editor-in-Chief Comments to Author:

Reviewer(s)' Comments to Author: Please consider the following comments in the revision of your manuscipt.

Reviewer: 1

Comments to the Author
GENERAL COMMENTS
The paper presents a retrospective chart review of pressure ulcer risk in individuals with spinal cord injury.

The paper appears to present an internal memo that has been slightly modified for submission. Acronyms are inconsistently and/or incorrectly used and several terms are used that are not defined. The study population was individuals or persons with SCI. The study cohort appears to be almost exclusively male and late middle-aged. This is unrepresentative of the SCI population as a whole or of the military personnel injured in recent conflicts. The study design is underdeveloped. The statistical methodology is weak. The validity of the findings presented is limited. The generalizability of the findings is unclear. There are several typographical errors and poorly structured sentences throughout the manuscript.
Specific comments and concerns are provided below.
SPECIFIC COMMENTS

Title: Please revise - The survey is of a spinal cord injury outpatient population.

Abstract
Define all acronyms at first use.
The Abstract states 120 records were reviewed – the Methods states it was 119. Please correct

Introduction
Define the term “veteran patients”. Does this mean individuals who were veterans or older persons.

Do not include full citations in the text

Define VA. If this for referring the Veterans Health Administration, the correct acronym is VHA

Provide references for the statements regarding recently injured military personnel and prognostic statements. Furthermore, since this is not the population studied here, this text belongs in the Discussion (implications of the study) rather than the background/introduction.

Avoid use of 1st person. Who is the “we” in this context? The individual with SCI who experiences the pressure ulcer? The caregiver who looks after the individual day to day in the community? Or the healthcare system and clinician who manage wound care?

The literature review includes outdated references, appears to be incomplete and does not appear to consider clinical practice guidelines.

The conflation of recurrent and severe is a logical fallacy.

It is stated that the goal of the study was to generate hypotheses.

Methods
The description of the study cohort is limited.

There is no power analysis to validate the sample size.

There is no CONSORT diagram to illustrate study recruitment procedures.

It is unclear whether the 1400 outpatients seen in the study timeframe were 1400 individuals.

The study title indicates a survey of an outpatient population. It is also stated that the annual exams may also occur when an individual is already hospitalized. This would appear to be a confounder and it is unclear whether these individuals were excluded.

How were ICD9 codes validated.

It does not appear that the study personnel consulted with clinical experts or Clinical Practice Guidelines in developing the data extraction tool.

Description of data collection training is limited to “how and where to find it”. Who provided this training? How was it validated? How was reliability determined if the extraction team members ‘worked together’. In order to validate initial data extraction, the same records should be accessed by different members of the team in a blinded manner and then compared.

The use of the term “the PI” is somewhat idiosyncratic in this context and does not inform the reader. What was the expertise applied. What is meant by “problematic cases”? How many of the records where “problematic cases”?

It would appear that a primary feature of the data resource used was that was unreliable. This would appear to be a case of building a castle on sand.

The description of the primary outcome is unclear and does not appear to be feasible to determine from a single assessment timepoint.

The authors do not appear to have consulted with clinicians with relevant expertise in order to develop critical variables. For example the ADA issued evidence-based nutrition practice guidelines which should be consulted when defining nutritional status in this population. BMI calculations must also be adjusted for the individual with SCI.

The treatment of missing data described is inappropriate. The authors are recommended to consult with a statistician with relevant expertise.

The statistical methodology is undeveloped.

There does not appear to have any test for normality.

There does not appear to have been any test applied to correct for repeated testing. This is essential when carrying out multiple statistical tests in order to avoid false positives.

Define HIPAA

Results
It is unclear why the authors did not over-sample in order to achieve a balanced study cohort.

Define “service connected status”

The relevance of time to heal to the study goals is unclear.

Please use clinically accepted standard acronyms: SCI level of injury is AIS (see American Spinal Injuries Association guidance)

FIM is known to be a poor indicator tool for the SCI population – was a modified version used?

Define “bed mobility”

Discussion
Provide references for the statement “advanced age has been identified as a PrU risk factor”. It has been established by Charlifue and others that aging per se is not a risk factor in this population.
Furthermore, the study cohort had a median age of 63yo, which is not considered advanced age in most societies. The relevance of this discussion is unclear.

Smoking did not reach statistical significance as a risk factor – the rationale behind a detailed discussion is unclear.

Provide references for statements such as “others have speculated”

The authors did not apply the correct methodology to determine BMI. The analysis should be re-done and the discussion re-visited.

The validity of the criterion for defining ‘caregiver’ is unclear. The presence of a bowel care program would appear to have several limitations as a surrogate measure.

Limitations: provide references for statements

Conclusion

The majority of the Conclusion would be more appropriate to include in the Discussion. The actual Conclusions are challenging to determine

Figures and Tables
Table 1: Age does not appear to match study timeframe. It is unclear how variables such as spasticity, pressure ulcer characteristics etc were determined. Other concerns with other variables noted above.
Code used is of limited value - delete

Table 2: Provide age range

Table 3: unclear why groups are unbalanced. Missing data rates should be provided for all variables.

Table 5: Internal document. Delete

Reviewer: 2

Comments to the Author
The topic of this manuscript is very important and highly relevant to persons with spinal cord injury and to their clinicians. The Author has made a good case that data regarding the development of pressure ulcers among those with spinal cord injury living in the community are lacking. Therefore, identifying risk factors, especially those which are reversible, would be highly desirable in this high-risk population.

Though the premise of this manuscript was excellent, there are significant methodological concerns that require clarification or further explanation:

1. While the Author described the use of the VA electronic medical record system as the source of data, he/she also referred to the "annual exam" data that were collected. Were the data extracted from only the information collected through the "annual exam" or throughout the entire electronic medical records of the subjects? For instance, were the number of pressure ulcers ("0" or ">1") determined just from this "annual exam", or were they from previous records too? From the "Results" section, it appeared that these were historical data which were not necessarily just from the "annual exam" but also from other history available from the electronic medical records system.

2. Since the data included previous/historical medical information, was there a defined study period? Or was data collected inclusive of any and all of the medical information of the subjects, regardless of the time interval from the "annual exam"?

3. Presumably the demographic data and the clinical characteristics were collected from the "annual exam" data from 2009. Some of these variables could presumably fluctuate much over time, e.g. pre-albumin level. Therefore, should a one-time assessment of such variables be used to measure or represent the clinical status of the subjects over a long period of time? Is it accurate and appropriate to study the correlation between a one-time assessment of potential risk factors and the development of pressure ulcers since the subjects' injury?

4. The use of certain variables requires more sophisticated definitions, e.g. spasticity is defined as "yes/no" and "medicated". These do not yield useful or accurate clinical information, rather than merely providing feasibility for statistical analysis. Similarly, for "caregiver" support, simply categorizing it as "0" or "1" by an ordinal scale does not represent accurately the whole spectrum of caregiver support that exists and thus the results may not be as meaningful.

5. Since this study focuses on those with SCI living in the community, it would be important to study variables which are specific to community-related issues. Unfortunately, the variables listed in this study do not seem to be specific to community issues that persons with SCI face. Once again, using caregiver support as an example, it would be a lost opportunity not to expand on and study in greater detail these variables which are so specific to those living in the community.

6. How was the number of 120 charts determined? Was it a convenience sample? Or was it statistically determined?

Clarification and additional information on these questions above are necessary to strengthen the methodology section, which is currently not sufficiently robust to convince this reviewer of the relevance of the findings.

Reviewer: 3

Comments to the Author
Thank you for this timely article on the very important subject of pressure ulcer prevention among Veterans with SCI.
I think this article could be revised slightly to include important missing information and expanded methods and limitation sections. Here are a few suggestions for revision: 1. Include results of power analysis for sample. 2. List stages of pressure ulcers (do you include Stage I?) and state if these stages of pressure ulcers were determined by a medical provider or lay caregiver. 3. Give more details of how colliniarity was determined and how the final variables were selected. Perhaps mention why the regression analysis was not based on current scientific knowledge for selecting the variables to include. 4. The nutrition variable does not seem adequately addressed. Albumin and pre-albumin are two unequal measures and there is no mention of how recent these lab values were drawn/recorded in relation to the evaluation. 5. Anemia is unclear - if this is determined by lab values alone, this needs to be described and list "cut-off" values and how recent these values are (is it a sustained anemia?) - or is it only a diagnosis of anemia on the chart? If this is the case, this should be listed as a limitation, since the medical diagnosis of anemia is frequently not listed, even when lab values support a diagnosis of anemia. 6. Consider using low BMI as proxy variable for poor nutrition, or see if these Veterans had a registered dietary evaluation as a better measure of nutritional status. 7. BMI should perhaps be separated into World Health Organization groupings or something better than obese and non-obese. 8. The uneven sample groups (with PrU vs. without PrU) should also be mentioned as a potential limitation. 9. If inpatients were part of this sample (the Veteran was an inpatient at the time of the evaluation), they should be listed - this study was aimed at outpatients, therefore if a significant number of inpatients were part of the cohort, especially if they developed pressure ulcers as an inpatient, this should be noted as a limitation of the study. 10. Level of

paralysis and current seating type and/or last wheelchair seating evaluation or recent weight/BMI change would have been important information for this study, especially since the authors are looking for potentially modifiable factors. Perhaps this could be included in the future study. Please see comments on attached article.